Attachment A

Attachment J.4.a: Summary of Massachusetts Schering-Plough Damages by Class and by Drug

(Excluding All Free Samples)

Class 2: Medicare Damages to Massachusetts Third-Party Payors

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre-Judgment Interest
Albuterol	0	0	6,964	72,807	146,428	280,045	412,287	442,468	530,625	546,159	440,648	394,588	254,917	157,837	0	0	3,685,774	5,863,438
Intron	3,342	3,927	4,242	4,135	3,308	9,416	11,179	8,758	7,050	9,479	9,457	11,933	12,686	13,755	0	0	112,666	185,898
Perphenazine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Proventil	23,356	64,346	52,724	16,866	13,244	8,078	1,718	0	0	0	0	58	0	0	0	0	180,389	443,172
Temodar	0	0	0	0	0	0	0	0	1,129	5,688	9,195	15,083	13,846	16,565	0	0	61,506	78,983
Total	26,698	68,273	63,930	93,809	162,980	297,539	425,183	451,226	538,804	561,326	459,300	421,662	281,449	188,156	0	0	4,040,335	6,571,490

Class 3: Non-Medicare Damages to Massachusetts Consumers and Third-Party Payors

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre-Judgment Interest
Albuterol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Intron	0	0	0	0	0	185	0	0	0	0	10,614	0	20,459	12,082	10,847	9,039	63,227	70,045
Perphenazine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Proventil	0	34,774	0	0	0	0	0	0	0	0	0	0	0	0	0	0	34,774	62,455
Temodar	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	0	34,774	0	0	0	185	0	0	0	0	10,614	0	20,459	12,082	10,847	9,039	98,001	132,499

Attachment J.4.b: Summary of National Schering-Plough Damages by Class and by Drug

(Excluding All Free Samples)

Class 2: Medicare Damages to National Third-Party Payors

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre-Judgment Interest
Albuterol	0	0	263,474	2,754,406	5,539,595	10,594,517	15,597,410	16,739,222	20,074,311	20,661,986	16,670,342	14,927,835	9,643,896	5,971,199	0	0	139,438,194	221,822,399
Intron	126,416	148,566	160,497	156,452	125,131	356,211	422,916	331,320	266,710	358,618	357,765	451,424	479,923	520,357	0	0	4,262,306	7,032,794
Perphenazine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Proventil	883,610	2,434,299	1,994,611	638,055	501,040	305,589	64,976	0	0	0	0	2,197	0	0	0	0	6,824,378	16,765,833
Temodar	0	0	0	0	0	0	0	0	42,709	215,182	347,872	570,629	523,802	626,675	0	0	2,326,869	2,988,025
Total	1,010,026	2,582,864	2,418,582	3,548,914	6,165,766	11,256,317	16,085,303	17,070,542	20,383,730	21,235,786	17,375,979	15,952,085	10,647,620	7,118,231	0	0	152,851,747	248,609,051

Class 3: Non-Medicare Damages to National Consumers and Third-Party Payors

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre-Judgment Interest
Albuterol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Intron	0	0	0	0	0	7,007	0	0	0	0	401,548	0	774,000	457,078	410,359	341,966	2,391,959	2,649,886
Perphenazine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Proventil	0	1,315,554	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1,315,554	2,362,749
Temodar	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	0	1,315,554	0	0	0	7,007	0	0	0	0	401,548	0	774,000	457,078	410,359	341,966	3,707,513	5,012,635

Attachment B

Remicade WAC Spread Analysis

(NDC: 57894003001, C168J REMICADE 1PCK US PD)

	1998	1999	2000	2001	2002	2003	Total
5% Margin Analysis (25% vs. 30% above WAC)							
1. WAC (AWP / 1.3)	$450.00	$470.25	$493.29	$532.01	$532.01	$532.01	
2. WAC + 25% (line 1 X 1.25)	$562.50	$587.82	$616.62	$665.01	$665.01	$665.01	
3. WAC + 30%: Actual AWP (line 1 X 1.3)	$585.00	$611.33	$641.28	$691.61	$691.61	$691.61	
4. Per Unit Dollar Difference (line 3 - line 2)	$22.50	$23.51	$24.66	$26.60	$26.60	$26.60	
5. Units	62,790	179,721	588,606	1,311,444	2,330,501	2,802,961	7,276,023
6. Total Dollars (line 4 X line 5)	$1,412,775	$4,225,725	$14,517,741	$34,884,915	$61,992,213	$74,559,841	$191,593,208
10% Margin Analysis (20% vs. 30% above WAC)							
1. WAC (AWP / 1.3)	$450.00	$470.25	$493.29	$532.01	$532.01	$532.01	
2. WAC + 20% (line 1 X 1.2)	$540.00	$564.30	$591.95	$638.41	$638.41	$638.41	
3. WAC + 30%: Actual AWP (line 1 X 1.3)	$585.00	$611.33	$641.28	$691.61	$691.61	$691.61	
4. Per Unit Dollar Difference (line 3 - line 2)	$45.00	$47.03	$49.33	$53.20	$53.20	$53.20	
5. Units	62,790	179,721	588,606	1,311,444	2,330,501	2,802,961	7,276,023
6. Total Dollars (line 4 X line 5)	$2,825,550	$8,451,449	$29,035,481	$69,769,830	$123,984,425	$149,119,681	$383,186,416

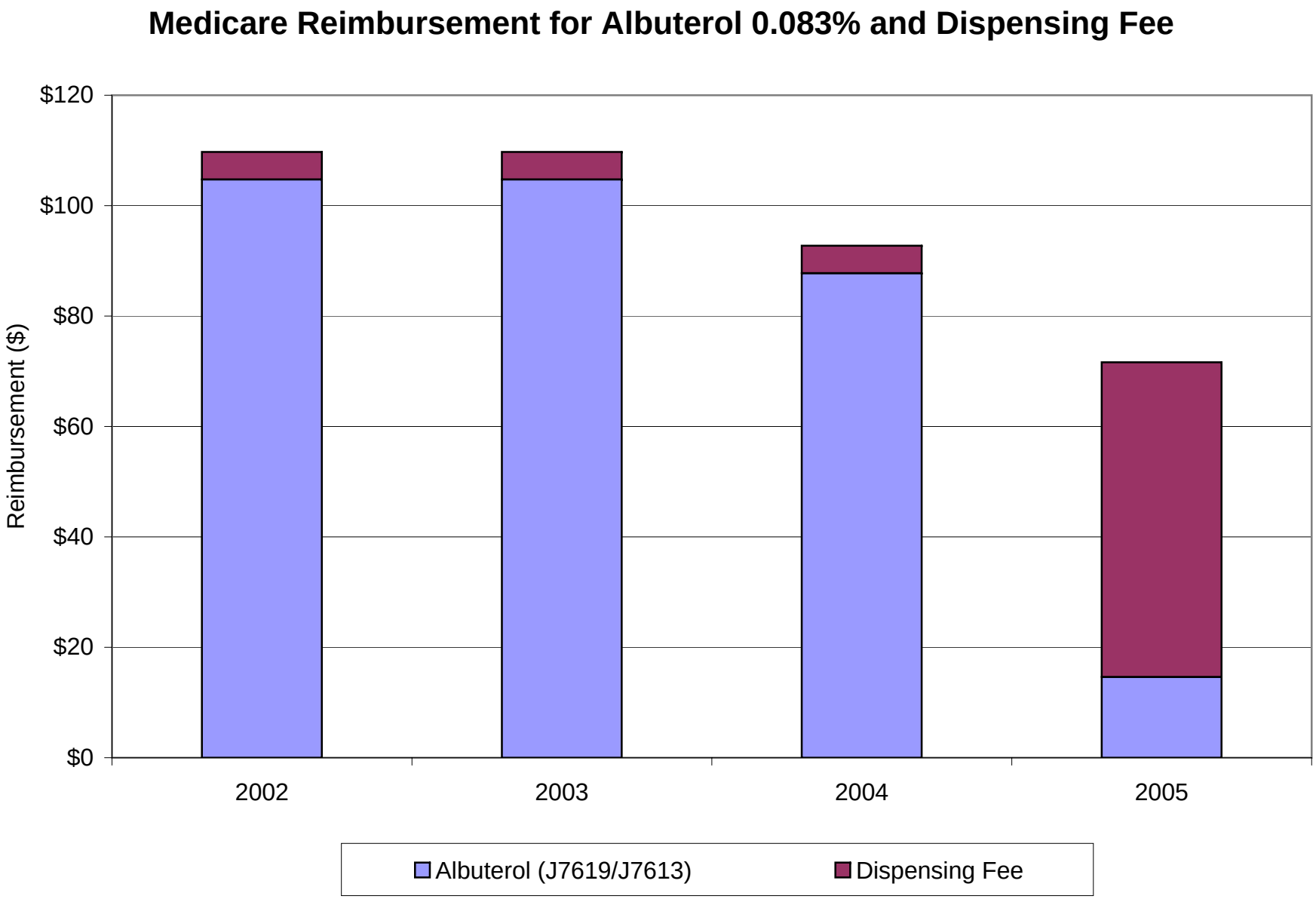
Notes:

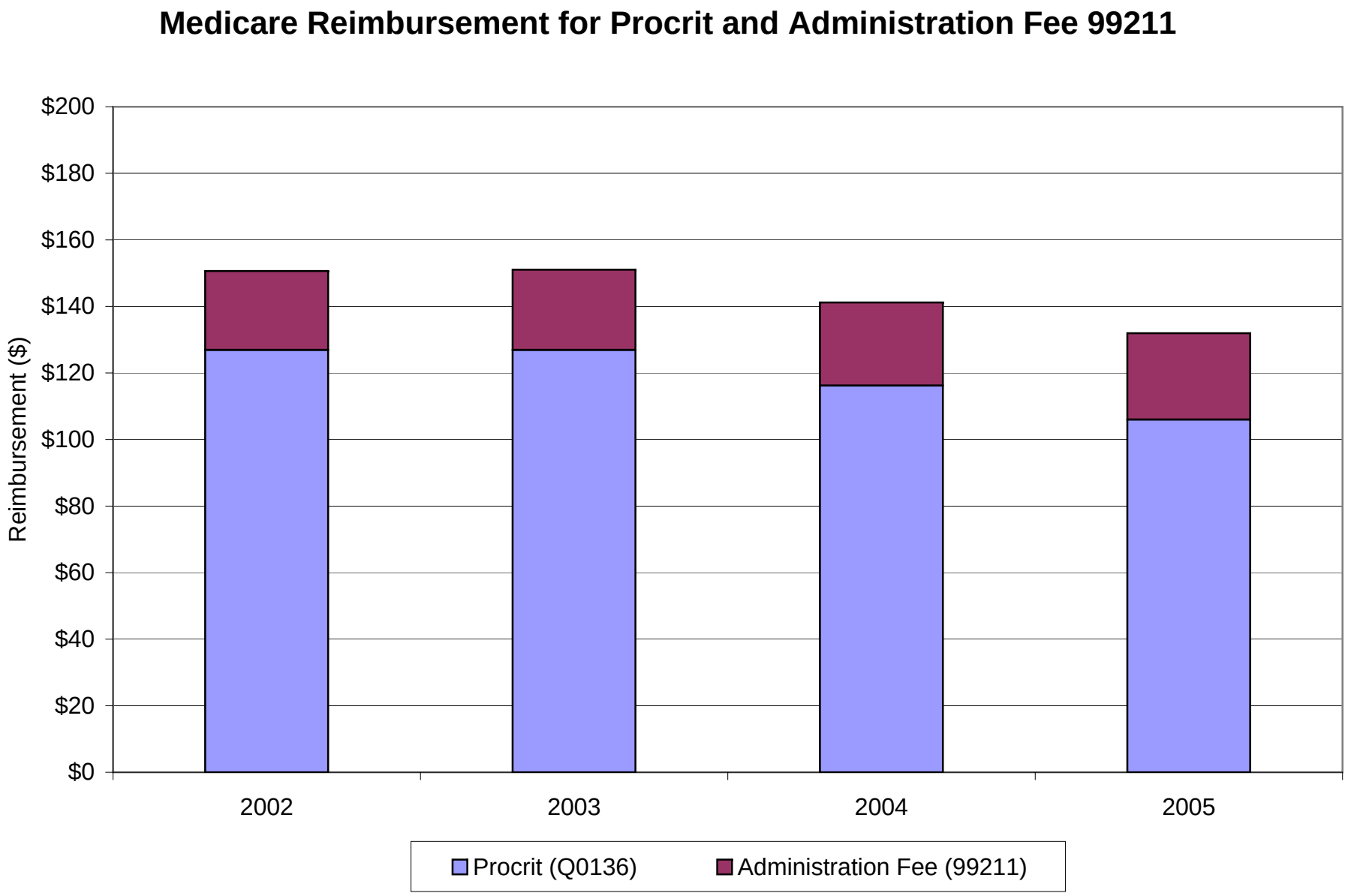
1. Units are those used in the most recent Johnson & Johnson damages analysis. All units excluded from the damages analysis are also excluded here.

2. FirstDataBank shows that the Remicade AWP is 30% above WAC. Procrit AWPs are typically 20% above WAC, but this spread increases to 25% in 2004.

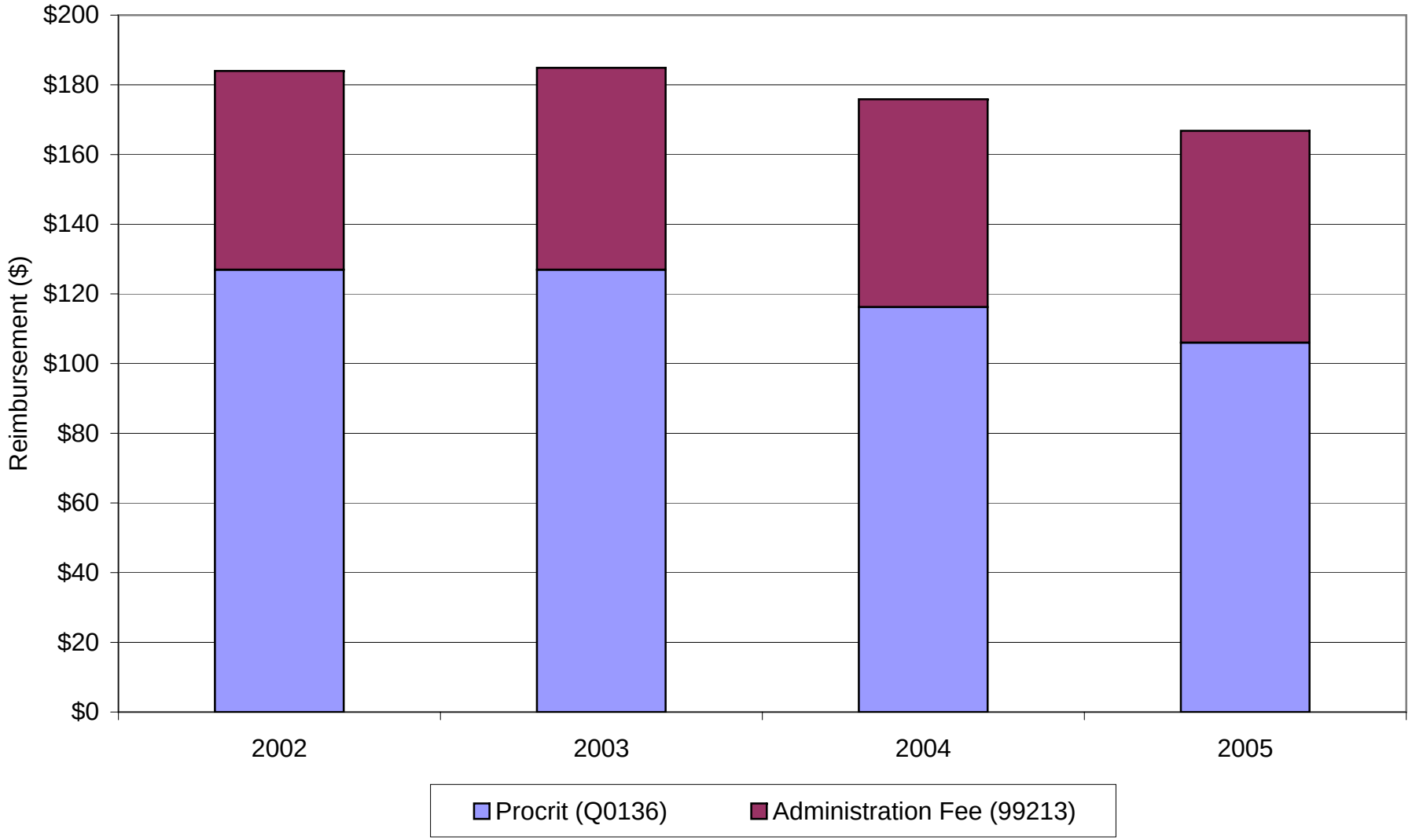
3. Annual AWP is the Red Book AWP as of June 30th in each year.

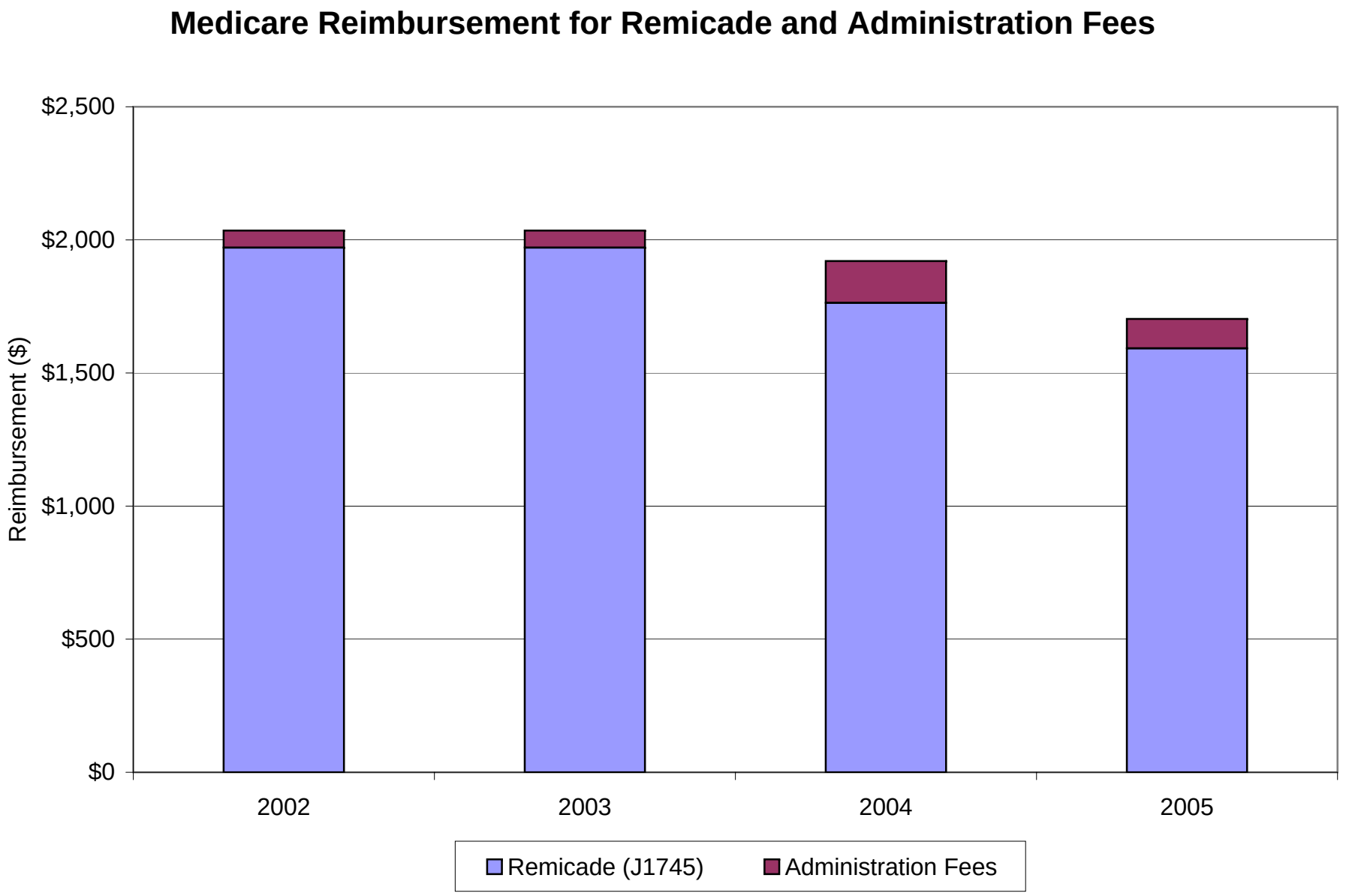
Attachment C

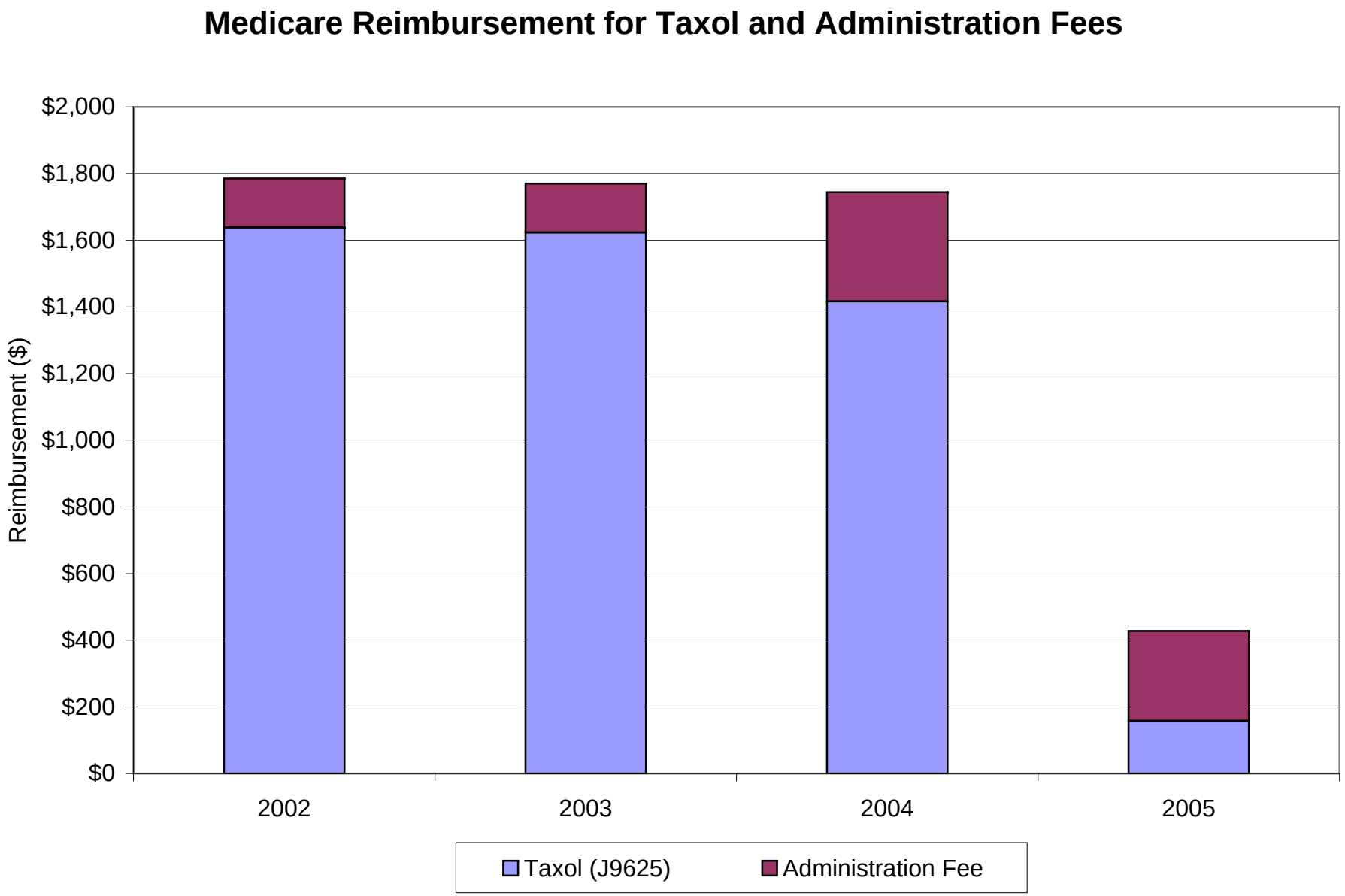

Medicare Reimbursement for Albuterol 0.083% and Dispensing Fee
Reimbursement ($)
$120
$100
$80
$60
$40
$20
$0
2002
2003
2004
2005
Albuterol (J7619/J7613)
Dispensing Fee

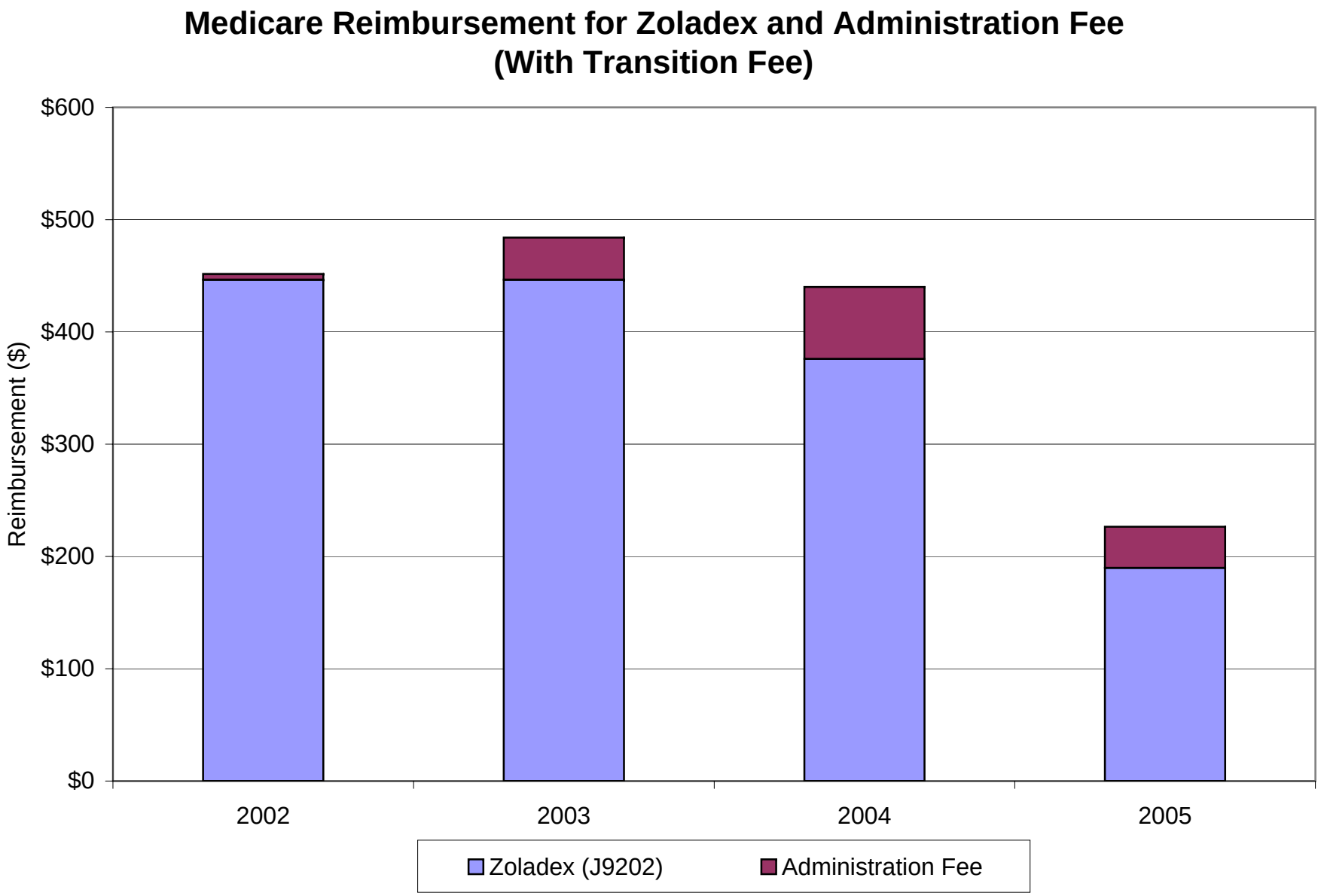

Medicare Reimbursement for Procrit and Administration Fee 99211
Reimbursement ($)
$200
$180
$160
$140
$120
$100
$80
$60
$40
$20
$0
2002
2003
2004
2005
Procrit (Q0136)
Administration Fee (99211)

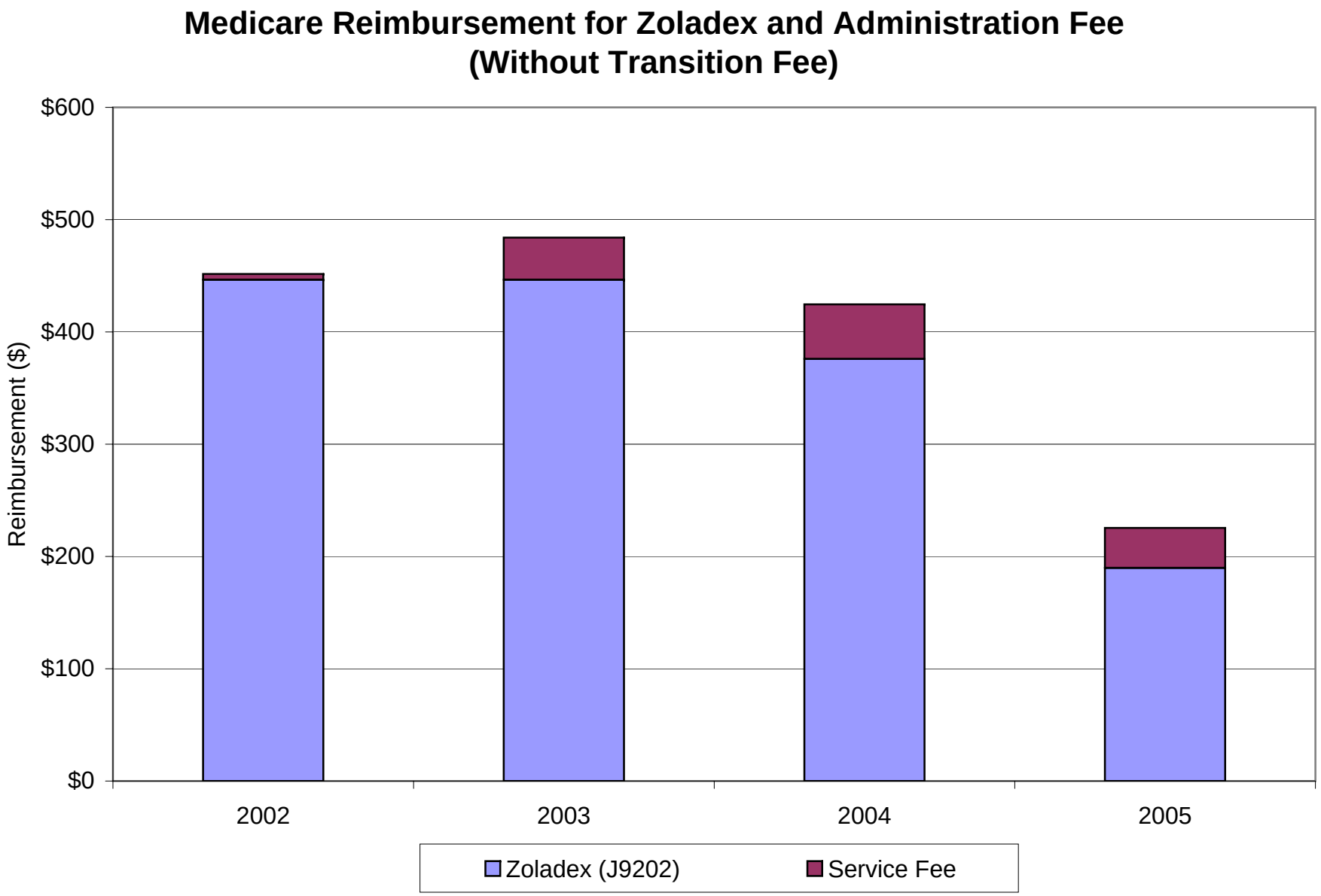
Medicare Reimbursement for Procrit and Administration Fee 99213




Medicare Reimbursement for Remicade and Administration Fees
Reimbursement ($)
$2,500
$2,000
$1,500
$1,000
$500
$0
2002
2003
2004
2005
Remicade (J1745)
Administration Fees


Medicare Reimbursement for Taxol and Administration Fees
Reimbursement ($)
$2,000
$1,800
$1,600
$1,400
$1,200
$1,000
$800
$600
$400
$200
$0
2002
2003
2004
2005
Taxol (J9625)
Administration Fee


Medicare Reimbursement for Zoladex and Administration Fee
(With Transition Fee)
Reimbursement ($)
$600
$500
$400
$300
$200
$100
$0
2002
2003
2004
2005
Zoladex (J9202)
Administration Fee


Medicare Reimbursement for Zoladex and Administration Fee
(Without Transition Fee)
$600
$500
$400
$300
$200
$100
$0
Reimbursement ($)
2002
2003
2004
2005
Zoladex (J9202)
Service Fee

Attachment D

An Accounting of Dr. Bell's Source of Pricing Information

Slide 29: Publications Prior to 1998 (Exhibit E)

Physician Administered Drugs

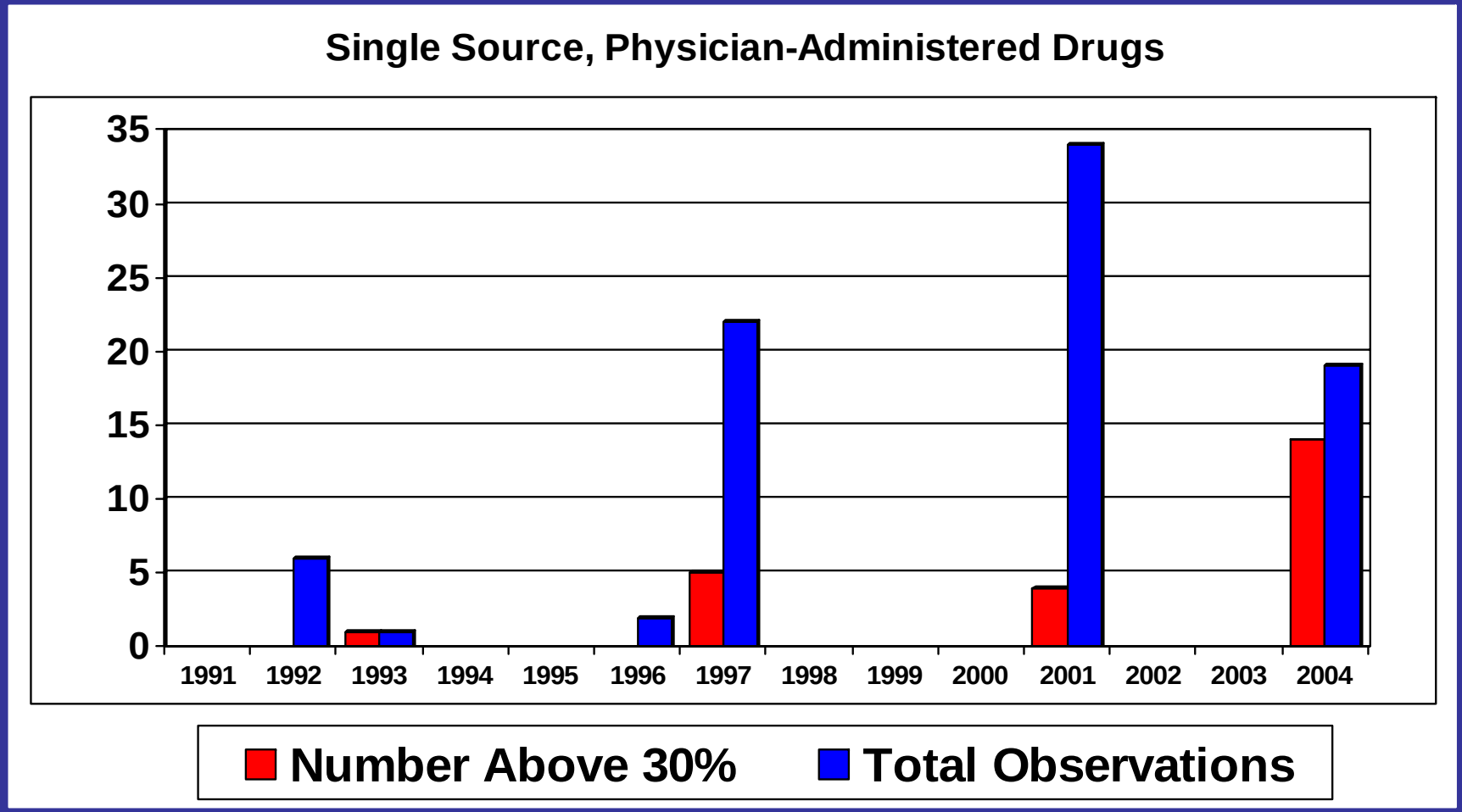
Source of Pricing Information	Count	Count over 30%	Count Using Averages Only	Count Over 30%
Excessive Medicare Payments for Prescription Drugs, OIG-HHS, Dec 1997.	78	20	22	5
Cost of Dialysis-Related Drugs, OIG-HHS, Oct 1992.	44	8	2	0
Physicians' Costs for Chemotherapy Drugs, OIG-HHS, Nov 1992.	12	0	4	0
Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in IL and MD, GAO, Mar 1993.	12	9	1	1
Alpert, Bill. Hooked on Drugs, Barron's. June 10, 1996, p15-16,18.	1	1	2	0
Subtotal Observations for Single Source	**147**	**38**	**31**	**6**

Attachment E

Number of Observations of Drug-Specific Average Spreads

Available from Public Sources

Count of Hartman Spreads > 30%



Source: Dr. Bell's Exhibit C and Underlying Data.xls with revisions.

Dr. Bell's Source of Observations

Publications Through 2004

Single-Source, Physician Administered Drugs

ID	Publication	Drugs	Below 30%	Above 30%	Total
BH 02	Physicians' Costs for Chemotherapy Drugs, OIG-HHS, Nov 1992.	6	12	0	12
Bell 03	Cost of Dialysis-Related Drugs, OIG-HHS, Oct 1992.	2	36	8	44
Bell 04	Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in IL and MD, GAO, Mar 1993.	3	3	9	12
BH 03	Alpert, Bill. Hooked on Drugs, Barron's. June 10, 1996, p15-16,18.	1	0	1	1
BH 04	Excessive Medicare Payments for Prescription Drugs, OIG-HHS, Dec 1997.	13 x 2y	58	20	78
Bell 06	High Cost Drugs Under the Outpatient Prospective Payment System, Kathpal Technologies, Sep 8, 1999.	34	12	48	60
BH 07	Medicare Reimbursement of Prescription Drugs, OIG-HHS, Jan 2001.	18	15	3	18
BH 08	Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, GAO, Sep 2001.	16	20	6	26
Bell 12	Medicare Part B: Program Payments Should Reflect Market Prices, GAO, Sep 21, 2001.	1	0	1	1
Bell 14	Japsen, Bruce, Medicare drug payment reform may not sting oncologists, Chicago Tribune, September 25, 2001.	1	1	0	1
Bell 17	Cancer Drugs Face Funds Cut in a Bush Plan, NY Times, August 6, 2003, p. 1	2	1	1	2
BH 12	Medicare Chemotherapy Payments: New Drug and Administration Fees are Closer to Providers' Costs, GAO, Dec 2004.	12	4	8	12
Bell 19	Medicare Reimbursement for Existing ESRD Drugs, OIG-HHS, May 2004.	6	3	9	12
	TOTAL		**165**	**114**	**279**

Source: Dr. Bell's Exhibit C and Underlying Data.xls

Comments on Dr. Bell's Choice of Observations

Publications Through 2004

Single-Source, Physician Administered Drugs

ID	Publication	Comment
BH 02	Physicians' Costs for Chemotherapy Drugs, OIG-HHS, Nov 1992.	Include manufacturer invoices only. Exclude oncology wholesalers.
Bell 03	Cost of Dialysis-Related Drugs, OIG-HHS, Oct 1992.	Use median instead of observations across multiple facilities
Bell 04	Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in IL and MD, GAO, Mar 1993.	Exclude all Medicaid SAD.
BH 03	Alpert, Bill. Hooked on Drugs, Barron's. June 10, 1996, p15-16,18.	Taxol and Platinol identified as Single-Source. Classify Immune Globulin as Multi-Source
BH 04	Excessive Medicare Payments for Prescription Drugs, OIG-HHS, Dec 1997.	Exclude "Highest" and "Lowest" outliers. Classify Epoetin Alpha and Immune Globulin as Multi-Brand.
Bell 06	High Cost Drugs Under the Outpatient Prospective Payment System, Kathpal Technologies, Sep 8, 1999.	Exclude. OPPS for hospitals.
BH 07	Medicare Reimbursement of Prescription Drugs, OIG-HHS, Jan 2001.	Classify Immune Globulin as Multi-Source
BH 08	Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, GAO, Sep 2001.	Exclude Table 5. Repeats calculation of spreads on subset of providers. Classify Paciltaxel and Epoetin Alpha as Single-Source
Bell 12	Medicare Part B: Program Payments Should Reflect Market Prices, GAO, Sep 21, 2001.	Exclude. Testimony. Repeats previous finding (BH 08)
Bell 14	Japsen, Bruce, Medicare drug payment reform may not sting oncologists, Chicago Tribune, September 25, 2001.	News story on TAP investigation.
Bell 17	Cancer Drugs Face Funds Cut in a Bush Plan, NY Times, August 6, 2003, p. 1	Exclude. News story. Repeats previous finding (BH 08).
BH 12	Medicare Chemotherapy Payments: New Drug and Administration Fees are Closer to Providers' Costs, GAO, Dec 2004.	Late in Class Period. Classify Epoetin Alpha as Single-Source
Bell 19	Medicare Reimbursement for Existing ESRD Drugs, OIG-HHS, May 2004.	Late in Class Period. Choose Table 1 to be conservative. "...independent dialysis facilities are reimbursed..95% of AWP"

Unique Observations of Average Spreads

From Publications Through 2004

Single-Source, Physician Administered Drugs

ID	Publication	Drugs	Below 30%	Above 30%	Total
BH 02	Physicians' Costs for Chemotherapy Drugs, OIG-HHS, Nov 1992.	4	4	0	4
Bell 03	Cost of Dialysis-Related Drugs, OIG-HHS, Oct 1992.	2	2	0	2
Bell 04	Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in IL and MD, GAO, Mar 1993.	1	0	1	1
BH 03	Alpert, Bill. Hooked on Drugs, Barron's. June 10, 1996, p15-16,18.	2	2	0	2
BH 04	Excessive Medicare Payments for Prescription Drugs, OIG-HHS, Dec 1997.	11 x 2y	17	5	22
Bell 06	High Cost Drugs Under the Outpatient Prospective Payment System, Kathpal Technologies, Sep 8, 1999.	-	-	-	-
BH 07	Medicare Reimbursement of Prescription Drugs, OIG-HHS, Jan 2001.	17	15	2	17
BH 08	Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, GAO, Sep 2001.	16	14	2	16
Bell 12	Medicare Part B: Program Payments Should Reflect Market Prices, GAO, Sep 21, 2001.	-	-	-	-
Bell 14	Japsen, Bruce, Medicare drug payment reform may not sting oncologists, Chicago Tribune, September 25, 2001.	1	1	0	1
Bell 17	Cancer Drugs Face Funds Cut in a Bush Plan, NY Times, August 6, 2003, p. 1	-	-	-	-
BH 12	'Medicare Chemotherapy Payments: New Drug and Administration Fees are Closer to Providers' Costs, GAO, Dec 2004.	13	4	9	13
Bell 19	'Medicare Reimbursement for Existing ESRD Drugs, OIG-HHS, May 2004.	6	1	5	6
	TOTAL		**60**	**24**	**84**

Note: With revisions as noted in previous slide.

Attachment F

Enclosure A

REBATE AGREEMENT
Between
The Secretary of Health and Human Services
(hereinafter referred to as "the Secretary")
and
The Manufacturer Identified in Section XI of this Agreement
(hereinafter referred to as "the Labeler")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labeler, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, hereby agree to the following:

I DEFINITIONS

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" means the AMP for the 7/l/90-9/30/90 quarter for purposes of computing the AMP as of 10/l/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act)

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f)"Centers for Medicare & Medicaid Services (CMS)" (formerly HCFA) means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g)"Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

(h) "Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d) (1) (3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.

(i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

(k) "Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

(l) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

(m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.

(n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC

number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(o) "National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

(q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

(s) "Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.

(t) "Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.

(u) "Quarter" means calendar quarter unless otherwise specified.

(v) "Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).

(w) "Secretary" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(y) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(z) "Single Source Drug" will have the meaning set forth in Section 1927 (k) (7) (A) (iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.

(aa) "States" means the 50 states and the District of Columbia.

(bb) "State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(cc) "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.

(dd) "Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

(ee) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with CMS's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

(b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.

(d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.

(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.

(g) To directly notify the States of a New Drug's Coverage.

(h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.

(i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

III SECRETARY'S RESPONSIBILITIES

(a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.

(b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.

(c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

IV PENALTY PROVISIONS

(a) The Secretary may impose a civil monetary penalty under III(b), up to $100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).

(b) The Secretary may impose a civil monetary penalty, in an amount not to exceed $100,000, for each item of false information as set forth in 1927(b)(3)(C)(i).

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

V DISPUTE RESOLUTION -- MEDICAID UTILIZATION INFORMATION

(a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).

(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).

(d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.

(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.

(f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

VI DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES

(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.

(b) Such compliance action by CMS will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

VII CONFIDENTIALITY PROVISIONS

(a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.

(b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

VIII NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).

(c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

IX GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Secretary will be sent to:

Center for Medicaid and State Operations
Family and Children's Health Programs Group
Division of Benefits, Coverage and Payment
Post Office Box 26686
Baltimore, MD 21207-0486

Notices to CMS concerning data transfer and information systems issues are to be sent to:

Center for Medicaid and State Operations
Finance, Systems and Quality Group
Division of State Systems
Post Office Box 26686
Baltimore, MD 21207-0486

The CMS address may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer notification to CMS at the address in this agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this agreement is automatically assigned to the new owner subject to the conditions specified in section 1927 and this agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or State laws.

(e) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.

(g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

X APPENDIX

Appendix A attached hereto is part of this agreement.

XI SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ _____
Date

Title: Deputy Director
Finance, Systems and Quality Group
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____ _____
(signature) (please print name)

Title: _____

Name of Manufacturer: _____

Manufacturer Address _____

_____

Manufacturer Labeler Code(s): _____

Date: _____